

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:)	Group Art Unit: 1634
)	
CUNNINGHAM <i>et al.</i>)	Examiner: Goldberg, J.
)	
Serial No. 09/954,695)	Atty. Docket No. GP116-02.UT
)	
Filed: September 11, 2001)	Confirmation No. 8611
)	
For: COMPOSITIONS, METHODS AND KITS)	
FOR DETERMINING THE PRESENCE)	
OF CRYPTOSPORIDIUM ORGANISMS)	
IN A TEST SAMPLE)	

RESPONSE TO RESTRICTION REQUIREMENT & AMENDMENT

Commissioner for Patents
Washington, D.C. 20231

Sir:

In response to the Examiner's Office Action mailed on November 22, 2002, in the above-captioned application, Applicants have amended the claims herein to recite a single group of related probe target sequences (SEQ ID Nos. 1-4), a single group of related helper oligonucleotide target sequences (SEQ ID Nos. 21, 23, 25 and 27), and a single group of related amplification primer target sequences (SEQ. ID. Nos. 48, 54, 60 and 66) in the independent claims. Each group of related target sequences includes a base DNA sequence, the DNA complement of the base sequence, and the RNA equivalents of the base sequence and its complement.

IN THE CLAIMS:

Please cancel claims 20, 22, 24-29, 42, 44, 46-49, 55-60, 63-70, 75-82, 84, 86, 87, and 89-91 without prejudice.

Kindly substitute and add the following claims:

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9. (Amended) The probe of claim 8, wherein said probe comprises two of said one or more base sequences, wherein said two base sequences hybridize to each other when said probe is not hybridized to the target sequence under the stringent conditions.

16. (Amended) A hybridization assay probe comprising an oligonucleotide which hybridizes to a target sequence present in nucleic acid derived from a *Cryptosporidium* organism in a test sample under stringent conditions to form a probe:target hybrid stable for detection, wherein said oligonucleotide has a base sequence which is at least 80% complementary to the base sequence of the target sequence, wherein the target sequence is selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3 and SEQ ID NO:4, and wherein said probe does not hybridize to nucleic acid derived from a non-*Cryptosporidium* organism in the test sample to form a probe:non-target hybrid stable for detection under the stringent conditions.

19. (Amended) A probe mix comprising the probe of claim 1 and a first helper oligonucleotide having an at least 10 contiguous base region which is at least 80% complementary to an at least 10 contiguous base region present in a target sequence, wherein the target sequence of said first helper oligonucleotide is selected from the group consisting of SEQ ID NO:21, SEQ ID NO:23, SEQ ID NO:25 and SEQ ID NO:27.

21. (Amended) The probe mix of claim 19 further comprising a second helper oligonucleotide having an at least 10 contiguous base region which is at least 80% complementary to an at least 10 contiguous base region present in a target sequence, wherein the target sequence of said second helper oligonucleotide is selected from the group consisting of SEQ ID NO:22, SEQ ID NO:24, SEQ ID NO:26 and SEQ ID NO:28.

23. (Amended) An amplification primer for use in amplifying a nucleic acid sequence present in nucleic acid derived from a *Cryptosporidium* organism under amplification

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conditions, said primer comprising an oligonucleotide having an at least 10 contiguous base region which is at least 80% complementary to an at least 10 contiguous base region present in a target sequence selected from the group consisting of SEQ ID NO:48, SEQ ID NO:54, SEQ ID NO:60 and SEQ ID NO:66, wherein said primer optionally includes a 5' sequence which is recognized by an RNA polymerase or which enhances initiation or elongation by an RNA polymerase.

38. (Amended) An amplification primer for use in amplifying a nucleic acid sequence present in nucleic acid derived from a *Cryptosporidium* organism under amplification conditions, said primer comprising an oligonucleotide having a base sequence which is at least 80% complementary to the base sequence of a target sequence selected from the group consisting of SEQ ID NO:48, SEQ ID NO:54, SEQ ID NO:60 and SEQ ID NO:66, and wherein said primer optionally includes a 5' sequence which is recognized by an RNA polymerase or which enhances initiation or elongation by an RNA polymerase.

39. (Amended) An amplification primer for use in amplifying a nucleic acid sequence present in nucleic acid derived from a *Cryptosporidium* organism under amplification conditions, wherein the base sequence of said primer is at least 80% complementary to the base sequence of a target sequence selected from the group consisting of SEQ ID NO:48, SEQ ID NO:54, SEQ ID NO:60 and SEQ ID NO:66, and wherein said oligonucleotide optionally includes a 5' sequence which is recognized by an RNA polymerase or which enhances initiation or elongation by an RNA polymerase.

40. (Amended) An amplification primer for use in amplifying a nucleic acid sequence present in nucleic acid derived from a *Cryptosporidium* organism under amplification conditions, wherein the base sequence of said primer is fully complementary to the base sequence of a target sequence selected from the group consisting of SEQ ID NO:48, SEQ ID NO:54, SEQ ID NO:60 and SEQ ID NO:66, and wherein said oligonucleotide optionally includes a 5' sequence which

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is recognized by an RNA polymerase or which enhances initiation or elongation by an RNA polymerase.

41. (Amended) A set of amplification primers for use in amplifying a nucleic acid sequence present in nucleic acid derived from a *Cryptosporidium* organism under amplification conditions, said set of primers including first and second primers, wherein:

said first primer is said primer of claim 23; and

said second primer comprises an oligonucleotide having an at least 10 contiguous base region which is at least 80% complementary to an at least 10 contiguous base region present in a target sequence selected from the group consisting of SEQ ID NO:45, SEQ ID NO:46, SEQ ID NO:51, SEQ ID NO:52, SEQ ID NO:57, SEQ ID NO:58, SEQ ID NO:63 and SEQ ID NO:64, wherein one or more primers of said set of primers optionally include a 5' sequence which is recognized by an RNA polymerase or which enhances initiation or elongation by an RNA polymerase.

43. (Amended) The primer set of claim 41, wherein the target sequence of said second primer is selected from the group consisting of SEQ ID NO:45, SEQ ID NO:51, SEQ ID NO:57 and SEQ ID NO:63.

45. (Amended) The primer set of claim 41, wherein the target sequence of said second primer is selected from the group consisting of SEQ ID NO:46, SEQ ID NO:52, SEQ ID NO:58 and SEQ ID NO:64.

74. (Amended) A kit comprising, in packaged combination, first and second oligonucleotides for use in determining the presence of a *Cryptosporidium* organism in a test sample,

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each of said oligonucleotides having an at least 10 contiguous base region which is at least 80% complementary to an at least 10 contiguous base region present in a target sequence contained in nucleic acid derived from a *Cryptosporidium* organism, wherein:

the target sequence of said first oligonucleotide is selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3 and SEQ ID NO:4;

the target sequence of said second oligonucleotide is selected from the group consisting of SEQ ID NO:48, SEQ ID NO:54, SEQ ID NO:60 and SEQ ID NO:66; and

said second oligonucleotide optionally includes a 5' sequence which is recognized by an RNA polymerase or which enhances initiation or elongation by an RNA polymerase.

83. (Amended) The kit of claim 74 further comprising a third oligonucleotide, wherein said third oligonucleotide has an at least 10 contiguous base region which is at least 80% complementary to an at least 10 contiguous base region present in a target sequence contained in nucleic acid derived from a *Cryptosporidium* organism, and wherein the target sequence of said third oligonucleotide is selected from the group consisting of SEQ ID NO:45, SEQ ID NO:51, SEQ ID NO:57 and SEQ ID NO:63.

85. (Amended) The kit of claim 74 further comprising a third oligonucleotide, wherein said third oligonucleotide has an at least 10 contiguous base region which is at least 80% complementary to an at least 10 contiguous base region present in a target sequence contained in nucleic acid derived from a *Cryptosporidium* organism, and wherein the target sequence of said third oligonucleotide is selected from the group consisting of SEQ ID NO:46, SEQ ID NO:52, SEQ ID NO:58 and SEQ ID NO:64.

88. (Amended) A kit comprising, in packaged combination, first and second oligonucleotides for use in determining the presence of a *Cryptosporidium* organism in a test sample, each of said oligonucleotides having an at least 10 contiguous base region which is at least 80%

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complementary to an at least 10 contiguous base region present in a target sequence contained in nucleic acid derived from a *Cryptosporidium* organism, wherein:

the target sequence of said first oligonucleotide is selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3 and SEQ ID NO:4; and

the target sequence of said second oligonucleotide is selected from the group consisting of SEQ ID NO:21, SEQ ID NO:23, SEQ ID NO:25 and SEQ ID NO:27.

92. (New) The probe of claim 16, wherein said oligonucleotide has a base sequence which is 100% complementary to the base sequence of the target sequence.

93. (New) A probe mix comprising the probe of claim 16 and a first helper oligonucleotide, wherein the base sequence of said first helper oligonucleotide is at least 80% complementary to the base sequence of a target sequence selected from the group consisting of SEQ ID NO:21, SEQ ID NO:23, SEQ ID NO:25 and SEQ ID NO:27.

94. (New) The probe mix of claim 93 further comprising a second helper oligonucleotide, wherein the base sequence of said second helper oligonucleotide is at least 80% complementary to the base sequence of a target sequence selected from the group consisting of SEQ ID NO:22, SEQ ID NO:24, SEQ ID NO:26 and SEQ ID NO:28.

95. (New) A probe mix comprising the probe of claim 17 and a first helper oligonucleotide, wherein the base sequence of said first helper oligonucleotide is at least 80% complementary to the base sequence of a target sequence selected from the group consisting of SEQ ID NO:21, SEQ ID NO:23, SEQ ID NO:25 and SEQ ID NO:27.

96. (New) The probe mix of claim 95 further comprising a second helper oligonucleotide, wherein the base sequence of said second helper oligonucleotide is at least 80%

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complementary to the base sequence of a target sequence selected from the group consisting of SEQ ID NO:22, SEQ ID NO:24, SEQ ID NO:26 and SEQ ID NO:28.

97. (New) A probe mix comprising the probe of claim 18 and a first helper oligonucleotide, wherein the base sequence of said first helper oligonucleotide is fully complementary to the base sequence of a target sequence selected from the group consisting of SEQ ID NO:21, SEQ ID NO:23, SEQ ID NO:25 and SEQ ID NO:27.

98. (New) The probe mix of claim 97 further comprising a second helper oligonucleotide, wherein the base sequence of said second helper oligonucleotide is fully complementary to the base sequence of a target sequence selected from the group consisting of SEQ ID NO:22, SEQ ID NO:24, SEQ ID NO:26 and SEQ ID NO:28.

99. (New) The primer of claim 38, wherein said oligonucleotide has a base sequence which is 100% complementary to the base sequence of the target sequence.

100. (New) A set of amplification primers for use in amplifying a nucleic acid sequence present in nucleic acid derived from a *Cryptosporidium* organism under amplification conditions, said set of primers including first and second primers, wherein:

said first primer is said primer of claim 38; and

said second primer comprises an oligonucleotide having a base sequence which is at least 80% complementary to the base sequence of a target sequence selected from the group consisting of SEQ ID NO:45, SEQ ID NO:46, SEQ ID NO:51, SEQ ID NO:52, SEQ ID NO:57, SEQ ID NO:58, SEQ ID NO:63 and SEQ ID NO:64.

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101. (New) The primer set of claim 100, wherein the target sequence of said second primer is selected from the group consisting of SEQ ID NO:45, SEQ ID NO:51, SEQ ID NO:57 and SEQ ID NO:63.

102. (New) The primer set of claim 100, wherein the target sequence of said second primer is selected from the group consisting of SEQ ID NO:46, SEQ ID NO:52, SEQ ID NO:58 and SEQ ID NO:64.

103. (New) A set of amplification primers for use in amplifying a nucleic acid sequence present in nucleic acid derived from a *Cryptosporidium* organism under amplification conditions, said set of primers including first and second primers, wherein:

said first primer is said primer of claim 39; and

said second primer comprises an oligonucleotide, wherein the base sequence of said primer is at least 80% complementary to the base sequence of a target sequence selected from the group consisting of SEQ ID NO:45, SEQ ID NO:46, SEQ ID NO:51, SEQ ID NO:52, SEQ ID NO:57, SEQ ID NO:58, SEQ ID NO:63 and SEQ ID NO:64.

104. (New) The primer set of claim 103, wherein the target sequence of said second primer is selected from the group consisting of SEQ ID NO:45, SEQ ID NO:51, SEQ ID NO:57 and SEQ ID NO:63.

105. (New) The primer set of claim 103, wherein the target sequence of said second primer is selected from the group consisting of SEQ ID NO:46, SEQ ID NO:52, SEQ ID NO:58 and SEQ ID NO:64.

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106. (New) A set of amplification primers for use in amplifying a nucleic acid sequence present in nucleic acid derived from a *Cryptosporidium* organism under amplification conditions, said set of primers including first and second primers, wherein:

said first primer is said primer of claim 40; and

said second primer comprises an oligonucleotide, wherein the base sequence of said primer is fully complementary to the base sequence of a target sequence selected from the group consisting of SEQ ID NO:45, SEQ ID NO:46, SEQ ID NO:51, SEQ ID NO:52, SEQ ID NO:57, SEQ ID NO:58, SEQ ID NO:63 and SEQ ID NO:64.

107. (New) The primer set of claim 106, wherein the target sequence of said second primer is selected from the group consisting of SEQ ID NO:45, SEQ ID NO:51, SEQ ID NO:57 and SEQ ID NO:63.

108. (New) The primer set of claim 106, wherein the target sequence of said second primer is selected from the group consisting of SEQ ID NO:46, SEQ ID NO:52, SEQ ID NO:58 and SEQ ID NO:64.

109. (New) The method of claim 51, wherein said oligonucleotide has a base sequence which is 100% complementary to the base sequence of the target sequence.

110. (New) The method of claim 54 further comprising a second amplification primer, said second primer comprising an oligonucleotide having an at least 10 contiguous base region which is at least 80% complementary to an at least 10 contiguous base region present in a target sequence selected from the group consisting of SEQ ID NO:45, SEQ ID NO:51, SEQ ID NO:57 and SEQ ID NO:63.

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111. (New) The method of claim 110 further comprising the step of determining the presence of the amplified target sequence in a test sample with a hybridization assay probe, wherein said probe comprises an oligonucleotide which hybridizes to the amplified target sequence under stringent conditions to form a probe:target hybrid stable for detection, said oligonucleotide having an at least 10 contiguous base region which is at least 80% complementary to an at least 10 contiguous base region present in the amplified target sequence, wherein the amplified target sequence is selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3 and SEQ ID NO:4, and wherein said probe does not hybridize to nucleic acid derived from a non-*Cryptosporidium* organism in the test sample to form a probe:non-target hybrid stable for detection under the stringent conditions.

112. (New) The method of claim 54 further comprising a second amplification primer, said second primer comprising an oligonucleotide having an at least 10 contiguous base region which is at least 80% complementary to an at least 10 contiguous base region present in a target sequence selected from the group consisting of SEQ ID NO:46, SEQ ID NO:52, SEQ ID NO:58 and SEQ ID NO:64.

113. (New) The method of claim 112 further comprising the step of determining the presence of the amplified target sequence in a test sample with a hybridization assay probe, wherein said probe comprises an oligonucleotide which hybridizes to the amplified target sequence under stringent conditions to form a probe:target hybrid stable for detection, said oligonucleotide having an at least 10 contiguous base region which is at least 80% complementary to an at least 10 contiguous base region present in the amplified target sequence, wherein the amplified target sequence is selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3 and SEQ ID NO:4, and wherein said probe does not hybridize to nucleic acid derived from a non-*Cryptosporidium* organism in the test sample to form a probe:non-target hybrid stable for detection under the stringent conditions.

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114. (New) The method of claim 71 further comprising the step of determining the presence of the amplified target sequence in a test sample with a hybridization assay probe, wherein said probe comprises an oligonucleotide which hybridizes to the amplified target sequence under stringent conditions to form a probe:target hybrid stable for detection, wherein said oligonucleotide has a base sequence which is at least 80% complementary to the amplified target sequence, wherein the amplified target sequence is selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3 and SEQ ID NO:4, and wherein said probe does not hybridize to nucleic acid derived from a non-*Cryptosporidium* organism in the test sample to form a probe:non-target hybrid stable for detection under the stringent conditions.

115. (New) The method of claim 71 further comprising a second amplification primer, said second primer comprising an oligonucleotide having a base sequence which is at least 80% complementary to a base sequence selected from the group consisting of SEQ ID NO:45, SEQ ID NO:51, SEQ ID NO:57 and SEQ ID NO:63.

116. (New) The method of claim 115 further comprising the step of determining the presence of the amplified target sequence in a test sample with a hybridization assay probe, wherein said probe comprises an oligonucleotide which hybridizes to the amplified target sequence under stringent conditions to form a probe:target hybrid stable for detection, wherein said oligonucleotide has a base sequence which is at least 80% complementary to the amplified target sequence, wherein the amplified target sequence is selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3 and SEQ ID NO:4, and wherein said probe does not hybridize to nucleic acid derived from a non-*Cryptosporidium* organism in the test sample to form a probe:non-target hybrid stable for detection under the stringent conditions.

117. (New) The method of claim 71 further comprising a second amplification primer, said second primer comprising an oligonucleotide having a base sequence which is at least

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80% complementary to a base sequence selected from the group consisting of SEQ ID NO:46, SEQ ID NO:52, SEQ ID NO:58 and SEQ ID NO:64.

118. (New) The method of claim 117 further comprising the step of determining the presence of the amplified target sequence in a test sample with a hybridization assay probe, wherein said probe comprises an oligonucleotide which hybridizes to the amplified target sequence under stringent conditions to form a probe:target hybrid stable for detection, wherein said oligonucleotide has a base sequence which is at least 80% complementary to the amplified target sequence, wherein the amplified target sequence is selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3 and SEQ ID NO:4, and wherein said probe does not hybridize to nucleic acid derived from a non-*Cryptosporidium* organism in the test sample to form a probe:non-target hybrid stable for detection under the stringent conditions.

119. (New) The method of claim 71, wherein said oligonucleotide has a base sequence which is 100% complementary to the base sequence of the target sequence.

120. (New) The method of claim 119 further comprising the step of determining the presence of the amplified target sequence in a test sample with a hybridization assay probe, wherein said probe comprises an oligonucleotide which hybridizes to the amplified target sequence under stringent conditions to form a probe:target hybrid stable for detection, wherein said oligonucleotide has a base sequence which is 100% complementary to the amplified target sequence, wherein the amplified target sequence is selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3 and SEQ ID NO:4, and wherein said probe does not hybridize to nucleic acid derived from a non-*Cryptosporidium* organism in the test sample to form a probe:non-target hybrid stable for detection under the stringent conditions.

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121. (New) The method of claim 119 further comprising a second amplification primer, said second primer comprising an oligonucleotide having a base sequence which is 100% complementary to a base sequence selected from the group consisting of SEQ ID NO:45, SEQ ID NO:51, SEQ ID NO:57 and SEQ ID NO:63.

122. (New) The method of claim 121 further comprising the step of determining the presence of the amplified target sequence in a test sample with a hybridization assay probe, wherein said probe comprises an oligonucleotide which hybridizes to the amplified target sequence under stringent conditions to form a probe:target hybrid stable for detection, wherein said oligonucleotide has a base sequence which is 100% complementary to the amplified target sequence, wherein the amplified target sequence is selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3 and SEQ ID NO:4, and wherein said probe does not hybridize to nucleic acid derived from a non-*Cryptosporidium* organism in the test sample to form a probe:non-target hybrid stable for detection under the stringent conditions.

123. (New) The method of claim 119 further comprising a second amplification primer, said second primer comprising an oligonucleotide having a base sequence which is 100% complementary to a base sequence selected from the group consisting of SEQ ID NO:46, SEQ ID NO:52, SEQ ID NO:58 and SEQ ID NO:64.

124. (New) The method of claim 123 further comprising the step of determining the presence of the amplified target sequence in a test sample with a hybridization assay probe, wherein said probe comprises an oligonucleotide which hybridizes to the amplified target sequence under stringent conditions to form a probe:target hybrid stable for detection, wherein said oligonucleotide has a base sequence which is 100% complementary to the amplified target sequence, wherein the amplified target sequence is selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3 and SEQ ID NO:4, and wherein said probe does not hybridize to nucleic

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acid derived from a non-*Cryptosporidium* organism in the test sample to form a probe:non-target hybrid stable for detection under the stringent conditions.

125. (New) The method of claim 72 further comprising the step of determining the presence of the amplified target sequence in a test sample with an oligonucleotide probe which hybridizes to the amplified target sequence under stringent conditions to form a probe:target hybrid stable for detection, wherein the base sequence of said probe is at least 80% complementary to the amplified target sequence, wherein the amplified target sequence is selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3 and SEQ ID NO:4, and wherein said probe does not hybridize to nucleic acid derived from a non-*Cryptosporidium* organism in the test sample to form a probe:non-target hybrid stable for detection under the stringent conditions.

126. (New) The method of claim 72 further comprising a second amplification primer, wherein the base sequence of said second primer is at least 80% complementary to a base sequence selected from the group consisting of SEQ ID NO:45, SEQ ID NO:51, SEQ ID NO:57 and SEQ ID NO:63.

127. (New) The method of claim 126 further comprising the step of determining the presence of the amplified target sequence in a test sample with an oligonucleotide probe which hybridizes to the amplified target sequence under stringent conditions to form a probe:target hybrid stable for detection, wherein the base sequence of said probe is at least 80% complementary to the amplified target sequence, wherein the amplified target sequence is selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3 and SEQ ID NO:4, and wherein said probe does not hybridize to nucleic acid derived from a non-*Cryptosporidium* organism in the test sample to form a probe:non-target hybrid stable for detection under the stringent conditions.

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128. (New) The method of claim 72 further comprising a second amplification primer, wherein the base sequence of said second primer is at least 80% complementary to a base sequence selected from the group consisting of SEQ ID NO:46, SEQ ID NO:52, SEQ ID NO:58 and SEQ ID NO:64.

129. (New) The method of claim 128 further comprising the step of determining the presence of the amplified target sequence in a test sample with an oligonucleotide probe which hybridizes to the amplified target sequence under stringent conditions to form a probe:target hybrid stable for detection, wherein the base sequence of said probe is at least 80% complementary to the amplified target sequence, wherein the amplified target sequence is selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3 and SEQ ID NO:4, and wherein said probe does not hybridize to nucleic acid derived from a non-*Cryptosporidium* organism in the test sample to form a probe:non-target hybrid stable for detection under the stringent conditions.

130. (New) The method of claim 73 further comprising the step of determining the presence of the amplified target sequence in a test sample with an oligonucleotide probe, wherein the base sequence of said probe is fully complementary to the base sequence of the amplified target sequence, and wherein the amplified target sequence is selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3 and SEQ ID NO:4.

131. (New) The method of claim 73 further comprising a second amplification primer, wherein the base sequence of said second primer is fully complementary to a base sequence selected from the group consisting of SEQ ID NO:45, SEQ ID NO:51, SEQ ID NO:57 and SEQ ID NO:63.

132. (New) The method of claim 131 further comprising the step of determining the presence of the amplified target sequence in a test sample with an oligonucleotide probe, wherein

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the base sequence of said probe is fully complementary to the base sequence of the amplified target sequence, and wherein the amplified target sequence is selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3 and SEQ ID NO:4.

133. (New) The method of claim 73 further comprising a second amplification primer, wherein the base sequence of said second primer is fully complementary to a base sequence selected from the group consisting of SEQ ID NO:46, SEQ ID NO:52, SEQ ID NO:58 and SEQ ID NO:64.

134. (New) The method of claim 133 further comprising the step of determining the presence of the amplified target sequence in a test sample with an oligonucleotide probe, wherein the base sequence of said probe is fully complementary to the base sequence of the amplified target sequence, and wherein the amplified target sequence is selected from the group consisting of SEQ ID NO:1, SEQ ID NO:2, SEQ ID NO:3 and SEQ ID NO:4.

135. (New) The kit of claim 74, wherein each of said oligonucleotides has a base region which is at least 80% complementary to the base sequence of the target sequence.

136. (New) The kit of claim 74, wherein each of said oligonucleotides has a base region which is 100% complementary to the base sequence of the target sequence.

137. (New) The kit of claim 74, wherein the base sequence of each of said oligonucleotides is at least 80% complementary to the base sequence of the target sequence.

138. (New) The kit of claim 74, wherein the base sequence of each of said oligonucleotides is fully complementary to the base sequence of the target sequence.

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139. (New) The kit of claim 83, wherein each of said oligonucleotides has a base region which is at least 80% complementary to the base sequence of the target sequence.

140. (New) The kit of claim 83, wherein each of said oligonucleotides has a base region which is 100% complementary to the base sequence of the target sequence.

141. (New) The kit of claim 83, wherein the base sequence of each of said oligonucleotides is at least 80% complementary to the base sequence of the target sequence.

142. (New) The kit of claim 83, wherein the base sequence of each of said oligonucleotides is fully complementary to the base sequence of the target sequence.

143. (New) The kit of claim 85, wherein each of said oligonucleotides has a base region which is at least 80% complementary to the base sequence of the target sequence.

144. (New) The kit of claim 85, wherein each of said oligonucleotides has a base region which is 100% complementary to the base sequence of the target sequence.

145. (New) The kit of claim 85, wherein the base sequence of each of said oligonucleotides is at least 80% complementary to the base sequence of the target sequence.

146. (New) The kit of claim 85, wherein the base sequence of each of said oligonucleotides is fully complementary to the base sequence of the target sequence.

147. (New) The kit of claim 88, wherein each of said oligonucleotides has a base region which is at least 80% complementary to the base sequence of the target sequence.

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148. (New) The kit of claim 88, wherein each of said oligonucleotides has a base region which is 100% complementary to the base sequence of the target sequence.

149. (New) The kit of claim 88, wherein the base sequence of each of said oligonucleotides is at least 80% complementary to the base sequence of the target sequence.

150. (New) The kit of claim 88, wherein the base sequence of each of said oligonucleotides is fully complementary to the base sequence of the target sequence.

151. (New) The kit of claim 88 further comprising a third oligonucleotide, wherein said third oligonucleotide has an at least 10 contiguous base region which is at least 80% complementary to an at least 10 contiguous base region present in a target sequence contained in nucleic acid derived from a *Cryptosporidium* organism, and wherein the target sequence of said third oligonucleotide is selected from the group consisting of SEQ ID NO:22, SEQ ID NO:24, SEQ ID NO:26 and SEQ ID NO:28.

152. (New) The kit of claim 151, wherein each of said oligonucleotides has a base region which is at least 80% complementary to the base sequence of the target sequence.

153. (New) The kit of claim 151, wherein each of said oligonucleotides has a base region which is 100% complementary to the base sequence of the target sequence.

154. (New) The kit of claim 151, wherein the base sequence of each of said oligonucleotides is at least 80% complementary to the base sequence of the target sequence.

155. (New) The kit of claim 151, wherein the base sequence of each of said oligonucleotides is fully complementary to the base sequence of the target sequence.

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Claims 1-19, 21, 23, 30-41, 43, 45, 50-54, 61, 62, 71-74, 83, 85, 88 and 92-155 are presently pending in the subject application.

Claims 20, 22, 24-29, 42, 44, 46-49, 55-60, 63-70, 75-82, 84, 86, 87, and 89-91 are canceled herein without prejudice to the prosecution of the subject matter of these claims in this or a future continuing application.

Claims 92-155 are newly added herein and find support in the specification and in the originally filed claims. No new matter is being added by the inclusion of these claims.

A marked-up version of the amendments is attached hereto in accordance with the provisions set forth in 37 C.F.R. § 1.121.

In response to the Examiner's Restriction Requirement, Applicants hereby elect the related sequences of SEQ ID Nos. 1-4 as the basis for the claimed hybridization assay probes, the related sequences of SEQ ID Nos. 21, 23, 25 and 27 as the basis for the helper oligonucleotides claimed in combination with the elected hybridization assay probes, and the related sequences of SEQ ID Nos. 48, 54, 60 and 66 as the basis for the amplification primers claimed alone or in combination with the elected hybridization assay probes. The independent claims have been amended in accordance with these elections. Amended and newly added dependent claims recite additional helper oligonucleotides and amplification primers, as allowed by the Examiner during a telephone interview with Applicants' representative on or about December 12, 2002.

Applicants submit that the subject application is in condition for allowance and early Notice to that effect is earnestly solicited.

Please charge the excess claims fee due under 37 C.F.R. § 1.16(c), and any other fee which may be due, to Deposit Account No. 07-0835 in the name of Gen-Probe Incorporated.

RESPONSE

Serial No. 09/954,695
Atty. Docket No. GP116-02.UTCertificate of Transmission

I hereby certify that this correspondence (and any referred to as attached) is being sent by facsimile to 703-872-9306 on the date indicated below to the Commissioner for Patents, Washington, D.C. 20231.

Respectfully Submitted,



Date: December 19, 2002

By: _____

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